

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

PCT/EP2005/050502

Re. item III**No opinion is established with respect to novelty, inventive step and industrial applicability**

- 1 The present application is based on a purely administrative task, namely the quality control of medical data records collected from different but comparable patient collectives during a medical project.
The object of the present application is to improve the quality control for medical data records collected during a medical project. The object is achieved by a method for carrying out quality control of medical data records collected from different but comparable patient collectives during a medical project, having the following steps:
a quality control parameter assigned to each data record is determined in the same manner;
the quality control parameters are evaluated on the basis of comparison criteria. It is assumed for comparable patient collectives that their key characteristics with respect to the data collection are identical, for example the same age and gender structure, ethnic origin, blood group, disease diagnosis, comorbid conditions and disease stage. Different means that they are composed of different individuals as patients, or are located at different clinics, or supervised by different clinicians.
- 1.1 The solution described in claim 1 is concerned with a purely administrative procedure which is based on predefined rules. Claim 1 does not disclose any technical means for performing the subject-matter of the claim.
Consequently, the subject-matter of claim 1 defines only a method for business operations as such.
- 1.2 Even if the subject-matter of claim 1 were to be interpreted in such a way as to define the technical features for the implementation of the method disclosed in the application, such a subject-matter would not be based on an inventive step, because it does not go beyond the simple automation of the administrative procedure on a conventional data processing system.

- 1.3 With respect to the technical implementation, the application discloses only the use of a database having a conventional technical mode of operation. These technical features characterize only generic means for data processing. At the priority date of the application, a data processing system having the above technical features belongs to the generally known prior art. Consequently, in the present case a conventional computer would be regarded as the closest prior art. No written evidence would be required for the existence of such a computer at the priority date.
- 1.4 The subject-matter of such a claim would then differ from the closest prior art only by virtue of the administrative aspects of the method for carrying out quality control of medical data records collected during a medical project.
- 1.5 The objective technical object would consequently consist of implementing the administrative procedure on the conventional computer.
- 1.6 The person skilled in the art is always an expert in a technical field. If the object relates to the implementation of an administrative task on a computer, the person skilled in the art is a person skilled in the art in the field of data processing and not an expert in the administrative field.
- 1.7 The technical means required for the implementation emerge directly from the specification on which the administrative model is based. In this case it would be possible to derive any technical considerations with respect to the implementation of the individual method steps on a conventional computer directly from the closest prior art. Such a technical solution would not go beyond the simple automation of the boundary conditions resulting from the administration model. An automation that is based solely on conventional hardware and programming techniques is obvious to the person skilled in the art. The implementation of the data processing steps determined by the administrative procedure within the abovementioned conventional computer would require no technical considerations that went beyond the standard actions of a person skilled in the art. The person skilled in the art would

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therefore arrive at the subject-matter of the claims without any inventive assistance.